

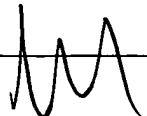


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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO.        |
|--|-------------|----------------------|---------------------|-------------------------|
| 10/761,978   | 01/21/2004  | Howard Cohen         | 479-P-007B          | 4044                    |
| 7277   | 7590        | 07/08/2004           | EXAMINER            |                         |
| HOWARD C. MISKIN<br>C/O STOLL, MISKIN, & BADIE<br>THE EMPIRE STATE BUILDING<br>350 FIFTH AVENUE SUITE 4710<br>NEW YORK, NY 10118 |             |                      |                     | SNOW, BRUCE EDWARD      |
| ART UNIT   |             | PAPER NUMBER         |                     |                         |
| 3738   |             |                      |                     | DATE MAILED: 07/08/2004 |

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |  |  |
|------------------------------|------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b>  |  |
|                              | 10/761,978             | COHEN ET AL.<br> |  |
| <b>Examiner</b>              | <b>Art Unit</b>        |  |  |
| Bruce E Snow                 | 3738                   |  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-37 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

DETAILED ACTION

***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-26, drawn to an artificial disc, classified in class 623, subclass 17.11.
  - II. Claims 27-37, drawn to a method of employing an artifical disc, classified in class 128, subclass 898.
2. The inventions are distinct, each from the other because of the following reasons:  
Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP ' 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using not requiring a bioresorbable material inserted between vertebral end plates or the product can be utilized to adjust a length of a long bone.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

***Election of Species***

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

**Select one of the following disc configurations:**

species 1 - figure 1

species 2 - figure 3

species 3 - figure 5

species 4 - figure 6

species 5 - figure 7

species 6 - figure 9

species 7 - figure 10A

species 8 - figure 11A

species 9 - figure 12A

species 10 - figure 13A

species 11 - figure 14A

species 12 - figure 14B

species 13 - figure 15A

species 14 - figure 16

species 15 - figure 17A

species 16 - figure 17B

species 17 - figure 17C

species 18 - figure 18A

species 19 - figure 18B

species 20 - figure 18C

species 21 - figure 18D

species 22 - figure 18E

species 23 - figure 18F

species 24 - figure 18G

species 25 - figure 19

species 26 - figure 20A

species 27 - figure 20B

species 28 - figure 20C

species 29 - figure 20D

species 30 - figure 20E

species 31 - figure 20F

**Select one of the following substances:**

Species 1 – osseous integration and bone ingrowth

Species 2 – hemostatic drug eluting factors to control bleeding

Species 3 – anti-microbial drug eluting factors

Species 4 – anti-tumor drugs

Species 5 – pain-controlling factors

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, none are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, **and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP ' 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

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7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (703) 308-3255. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (703)308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW  
PRIMARY EXAMINER